Billing code: 4153-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0945-0003-60D]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0945-0003-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, Sherrette.funn@hhs.gov, or call 202-795-7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use

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of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR Parts 160 and 164

Type of Collection: Extension

OMB No. 0945-0003 – Office for Civil Rights (OCR) – Health Information Privacy Division

Abstract: Office for Civil Rights (OCR) requests approval to extend this existing, approved collection without changing any collecting requirements while OCR obtains public comment through a Notice of Proposed Rulemaking (NPRM) proposing modifications to the HIPAA Rules that will affect the hourly burdens associated with the Rules. When the NPRM is published, we expect to receive robust public comment on existing burdens associated with compliance with the HIPAA Rules and on changes in burden that could result from the modifications proposed in the NPRM. OCR will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

Likely Respondents: HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

Estimated Annualized Burden Hour Table

Forms	Respondents	Number of	Number of	Average	Total Burden
(If necessary)	(If necessary)	Respondents	Responses per	Burden per	Hours
			Respondents	Response	
45 CFR 160.204	A state's chief	1	1	16	16
	elected				
Process for	official or				
Requesting Exception	designee				
Determinations (states					
or persons)					
45 CFR 164.308	Covered	1,700,000	1	10	17,000,000
	entities;				
Risk Analysis -	business				
Documentation	associates				

45 CFR 164.308	Covered entities;	1,700,000	12	0.75	15,300,000
Information System	business				
Activity Review –	associates				
Documentation					
45 CFR 164.308	Covered	1,700,000	12	1	20,400,000
	entities;				
Security Reminders –	business				
Periodic Updates	associates				
45 CFR 164.308	Covered	1,700,000	52	5	442,000,000
	entities;				
Security Incidents	business				
(other than breaches)	associates				
 Documentation 					
45 CFR 164.308	Covered	1,700,000	1	8	13,600,000
	entities;				
Contingency Plan –	business				
Testing and Revision	associates				
45 CFR 164.308	Covered	1,700,000	1	4	6,800,000
	entities;				
Contingency Plan –	business				
Criticality Analysis	associates				
45 CFR 164.310	Covered	1,700,000	12	6	122,400,000
	entities;				
Maintenance Records	business				
45 CED 164 214	associates	1 000 000	10	20	240,000,000
45 CFR 164.314	Business associates	1,000,000	12	20	240,000,000
Security Incidents –	ussociates				
Business Associate					
reporting of incidents					
(other than breach) to					
Covered Entities					
45 CFR 164.316	Covered	1,700,000	1	6	10,200,000
	entities;	·			
Documentation –	business				
Review and Update	associates				
45 CFR 164.404	Covered	58,481	1	0.5	29,241
Individual Notice— Written and E-mail	entities				
Notice (drafting)					
Notice (draiting)					
45 CFR 164.404	Covered	58,481	1	0.5	29,241
	entities				
Individual Notice—					
Written and E-mail					

Notice (preparing and documenting notification)					
45 CFR 164.404	Covered	58,481	353	0.008	165,150
Individual Notice—	entities				
Written and E-mail					
Notice (processing					
and sending)	~ .	2.7.4			2.716
45 CFR 164.404	Covered entities	2,746	1	1	2,746
Individual Notice—	entities				
Substitute Notice					
(posting or					
publishing)		2515			15.500
45 CFR 164.404	Covered entities	2,746	1	5.75	15,790
Individual Notice—	entities				
Substitute Notice					
(staffing toll-free					
number)					
45 CFR 164.404	Covered entities	11,326,440	1	0.125	1,415,805
Individual Notice—	entities				
Substitute Notice					
(individuals'					
voluntary burden to					
call toll-free number for information)					
45 CFR 164.406	Covered	267	1	1.25	334
	entities	207	-	1.20	
Media Notice					
45 CFR 164.408	Covered	267	1	1.25	334
Notice to Secretary	entities				
(notice for breaches					
affecting 500 or more					
individuals)					
45 CFR 164.408	Covered	58,215	1	1	58,215
Notice to Secretary	entities				
(notice for breaches					
affecting <500					
individuals)					
45 CFR 164.410	Business	20	1	50	1,000
Business associate	associates				
notice to covered					
entity – 500 or more					
Affected Individuals					

45 CFR 164.410	Business associates	1,165	1	8	9,320
Business associate	associates				
notice to covered					
entity – Less than 500					
Affected Individuals					
45 CFR 164.414	Covered entities	267	1	50	13,350
500 or More Affected	Circleios				
Individuals					
(investigating and					
documenting breach)					
45 CFR 164.414	Covered	2,479	1	8	19,832
	entities				
Less than 500					
Affected Individuals					
(investigating and					
documenting breach)					
affecting 10-499 45 CFR 164.414	C1	55 727	1	4	222.044
45 CFR 164.414	Covered entities	55,736	1	4	222,944
Less than 500	entities				
Affected Individuals					
(investigating and					
documenting breach)					
affecting <10					
45 CFR 164.504	Covered	700,000	1	0.083333333	58,333
	entities				
Uses and Disclosures					
Organizational					
Requirements					
45 CFR 164.508	Covered	700,000	1	1	700,000
43 CFR 104.308	entities	700,000	1	1	/00,000
Uses and Disclosures	circies				
for Which Individual					
authorization is					
required					
1					
45 CFR 164.512	Covered	113,524	1	0.083333333	9,460
	entities				
Uses and Disclosures					
for Research Purposes					
45 CFR 164.520	Covered	100,000,000	1	0.004166667	416,667
N-4: CD:	entities –				
Notice of Privacy Practices for	health plans				
Protected Health					
Information (health					
plans – periodic					
distribution of NPPs					
by paper mail)					
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Notice of Privacy Practices for Protected Health Information (health plans – periodic distribution of NPPs by electronic mail) 45 CFR 164.520 Covered entities – health care providers dissemination and acknowledgment) 45 CFR 164.522 Rights to Request Privacy Protection for Protected Health Information 45 CFR 164.524 Covered entities – health care providers health care providers health care providers, health plans clearinghouses 45 CFR 164.526 Amendment of Protected Health Information (requests) 45 CFR 164.526 Covered entities – health care providers, health plans, clearinghouses 45 CFR 164.526 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health care providers, health plans, clearinghouses 45 CFR 164.528 Covered entities - health	45 CFR 164.520	Covered	100,000,000	1	0.002783333	278,333
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Disclosures of providers, health plans, Information clearinghouses TOTAL	Accounting for	health care				
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Information clearinghouses Control Con						
TOTAL OF TOTAL						
						921,824,027

TERRY CLARK

Office of the Secretary

Paperwork Reduction Act Reports Clearance Officer [FR Doc. 2019-15323 Filed: 7/18/2019 8:45 am; Publication Date: 7/19/2019]